

In response we point out the following support of these particular terms in the originally-filed specification. (1) "Anhydrous process" finds support in the specification at the examples section, where someone having ordinary skill in this art, with our written description in hand, would readily understand that the evaporation-extraction process of our invention must be conducted in the absence of water, and in the presence of organic solvents only, especially oil. It is clear from the disclosure that in order for the process to be effective it must be conducted in anhydrous conditions, and therefore the term "anhydrous" is fully appropriate. (2) "Biodegradable polymer" finds support in the specification at originally-filed claim 1 and the abstract as originally filed. (3) "First organic solvent" finds support in the specification in the description of the organic solvent acetonitrile, throughout the disclosure for instance at column 1, lines 20-21, column 2, lines 2-9. Someone having ordinary skill in this art, with our written description in hand, would understand that any organic solvent would be effective as long as the criteria that is affirmatively recited in claim 11, step a), i.e., "capable of dissolving the biodegradable polymer with one or both of a biologically active material and a biologically active material-stabilizer matrix." (4) "Second non-polar organic solvent suitable to extract residual first organic solvent" finds support in the specification at column 1, lines 50-53, column 2, lines 8-15, and column 3, lines 43-47. In addition, someone having ordinary skill in this art would recognize from the list of non-polar solvents of heptane, hexane, pentane and isopropanol in the specification that non-polar solvents are what is intended here. (5) "Biologically active material-stabilizer matrix" finds support in the specification at at originally-filed claim 1 and the abstract as originally filed, as well as column 1, lines 30-31 and column 3, lines 12-17.

In summary, all of the objected-to language is adequately supported by the written description as originally filed, and no new matter is introduced. Withdrawal of the rejection of claims 11-27 is therefore requested, and allowance of all claims 1-27 is believed to be in order.

Rejection of claims 11-27 under 37 C.F.R. §112, first paragraph

Claims 11-27 are rejected under 37 C.F.R. §112, first paragraph as allegedly failing to comply with the written description requirement. Specifically, the Examiner states that the following terms and phrases are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the invention at the time the application was filed: (1) anhydrous process; (2) biodegradable polymer; (3) first organic solvent; (4) second non-polar organic solvent suitable to extract residual first organic solvent; and (5) biologically active material-stabilizer matrix.

As noted above, these terms are supported by the application as filed. Someone having ordinary skill in this art would recognize that that inventors did in fact have possession of the invention at the time the application was filed.

In summary, all of the objected-to language is adequately supported by the written description as originally filed, and the requirements of §112, first paragraph are met. Withdrawal of the rejection of claims 11-27 is therefore requested, and allowance of all claims 1-27 is believed to be in order.

Having addressed the Examiner's concerns, this reissue application is believed to be in condition for allowance and notice to that effect is earnestly solicited. Applicants respectfully note that this reissue application has been pending since January 6, 2000—5½ years ago—and since its filing we have responded in good faith to four office actions and various other papers from the Patent Office. One time the application was erroneously found abandoned by the Patent Office and we were forced to file a petition. Once a response after final rejection was not matched with the file until more than two months after it was filed, forcing the applicants to resubmit the response and file an expensive notice of appeal just to maintain pendency. Throughout pendency, applicants' representative has had numerous telephone conversations with Examiner T. Criares, and one with his supervisor, to resolve any outstanding technical issues and issues of merit regarding the claims and the declaration. On three occasions, the latest being just prior to the filing of our last response on November 18, 2004, Examiner Criares reviewed the


Reissue Application 09/478,822  
Response dated August 25, 2005  
Reply to Office Action of April 29, 2005

claims over the telephone with applicants' representative, as well as the declaration, and found the claims to be allowable and the declaration to meet all requirements. The claim language was carefully gone over and found to be supported by the specification. During the last conversation between Examiner Criares and applicants' representative last year, Examiner Criares stated that all the claims and the supplemental declaration met all patentability criteria and other relevant rules. On the basis of Examiner Criares' direct affirmations to applicants' representative, the applicants filed the November 18, 2004 response with the claim language as it now stands.

Now, it appears that a new Examiner has been assigned to this case, and claim language that Examiner Criares had expressly found allowable and supported by the specification is objected to in this new office action for the first time, 5 ½ years after the application was filed. In addition, this is a reissue application and is entitled to special status for expedited examination, and any such basic objections, if any, on the order of new subject matter and written description deficiencies should have been raised at the outset of examination. Under any interpretation of the facts, it is clear that we have not been afforded the expedited examination that is proper. We urge the Examiner to recognize that this is an improper and unfair and unreasonably expensive and burdensome examination of this reissue application, and request urgently that this application be allowed since it has already been thoroughly examined.

If the Examiner has any further inquiries the Examiner is invited to contact Applicants' representative, the undersigned, at (301) 977-7227. **[PLEASE NOTE THAT THIS IS A NEW TELEPHONE NUMBER]**

Respectfully submitted,

  
Marlana K. Titus, Reg. No. 35,843

For Elizabeth Arwine, Reg. No. 45,867

Attorney for applicant

U.S. Army Medical Research and Materiel Command  
504 Scott Street, Ft. Detrick, MD 21702-5012

Nash & Titus, LLC  
6005 Riggs Road  
Laytonsville, MD 20882  
(301) 977-7227